K080115

510(K) SUMMARY

Date: May 29, 2008

MAY 30 2008

Contact Person: Jan D'Alise Martin
Director of Regulatory Affairs

Trade Name: **I-Mini Dental Implant**
Common Name: Endosseous Screw Implant
Classification Name: Dental Implant Endosseous / Code 76DZE

Substantial Equivalence to: IMTEC Sendax MDI (K031106)
BioHorizons Maestro System 3.0mm (K032351)

Description of Device: A self-tapping CP Titanium or Titanium Alloy threaded screw, with light grit blasting or roughened surface treatment.

Indications for Use: As an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implant may be immediately restored with a temporary prosthesis that is not in functional occlusion.

When splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors. The implants may be restored after a period of time or placed in immediate function.

For denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be restored after a period of time or placed in immediate function when good primary stability is achieved and with appropriate occlusal loading.

Substantial Equivalence: Substantial Equivalence for the **I-Mini Dental Implant** is based on the following comparison of predicate devices such as IMTEC Sendax MDI and the BioHorizons Maestro System. The design, function, labeling, material composition and intended use are equivalent to the devices currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 30 2008

OCO Biomedical, Incorporated
C/O Mr. Kevin Walls
Principal Consultant
Phoenix Regulatory Associates, Limited
Washington DC Headquarters
21525 Ridgetop Circle, Suite 240
Sterling, Virginia 20166

Re: K080115
Trade/Device Name: I-Mini Dental Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: May 13, 2008
Received: May 16, 2008

Dear Mr. Walls:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

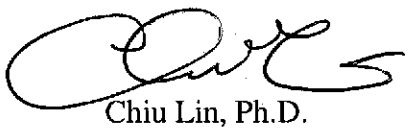
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080115

Device Name: I-Mini Dental Implant

Indications for Use:

As an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implant may be immediately restored with a temporary prosthesis that is not in functional occlusion.

When splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors. The implants may be restored after a period of time or placed in immediate function.

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080115